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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,571	05/23/2001	Thomas Himmler	M0-6341/LEA3	9929

7590 07/10/2003

Bayer Corporation  
400 Morgan Lane  
West Haven, CT 06516-4175

EXAMINER
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ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 07/10/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/856,571

Applicant(s)

HIMMLER ET AL.

Examiner

Binta M. Robinson

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 12-14 is/are rejected.
- 7) ☒ Claim(s) 5-11 and 15-24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 6) ☐ Other: \_\_\_\_.

### Detailed Action

The 112, second paragraph rejection of claims 13-14 are withdrawn in light of applicant's amendment at paper no. 12/C.

#### (old rejections)

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Himmler. (See Reference N) for reasons of record at paper no. 11.

Himmler et. al. teaches the instant compound, 3-Quinolinecarboxylic acid, 8-cyano-1-cyclopropyl-6-fluoro-1,4-dihydro(octahydro-6H-pyrrolo[3,4-b]pyridin-6-yl)-4-oxo-, monohydrochloride, (4aS-cis)--. At page 15, lines 16-20, see Beispiel 2. The difference between the prior art compound and the instantly claimed compounds is the extent of the salt formation. In the instant compound, the salt is semi-hydrochloride of 8-cyano-1-cyclopropyl-7-(1S, 6S-2, 8-diazabicyclo-[4, 3, 0]nonan-8-yl)-6-fluoro-1, 4-dihydro-4-oxo-3-quinolnecarboxylic acid. In the Himmler compound, the salt is a monohydrochloride of 8-cyano-1-cyclopropyl-7-(1S, 6S-2, 8-diazabicyclo-[4, 3, 0]nonan-8-yl)-6-fluoro-1, 4-dihydro-4-oxo-3-quinolnecarboxylic acid. It's axiomatic in organic chemistry that acids will react with bases to form salts. Since there are several nitrogen atoms present in the

Art Unit: 1625

instant compound, it is possible to form 1 to 3 acid-addition salts of HCL. It would have been obvious to one of ordinary skill to form a semihydrochloride from a monohydrochloride of the of 8-cyano-1-cyclopropyl-7-(1S, 6S-2, 8-diazabicyclo-[4, 3, 0]nonan-8-yl)-6-fluoro-1, 4-dihydro-4-oxo-3-quinolnecarboxylic acid. For instance, at page 15, lines 16-20 of the Himmeler reference, see Beispiel 2, where a disclosed species is exemplified. Accordingly, the compounds are deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed compounds over those of the generic prior art compounds.

Claims 5-11 and 15-24 are objected to because they are based on a rejected claim.

**Response to Applicant's Remarks**

The applicant traverses the 103 (a) rejection alleging that it is generally quite unpredictable which kind of salts a given compound may form. However, it's axiomatic in organic chemistry that acids will react with bases to form salts. Since there are several nitrogen atoms present in the instant compound, it is possible to form 1 to 3 acid-addition salts of HCL. It would have been obvious to one of ordinary skill to form a semihydrochloride from a monohydrochloride of the of 8-cyano-1-cyclopropyl-7-(1S, 6S-2, 8-diazabicyclo-[4, 3, 0]nonan-8-yl)-6-fluoro-1, 4-dihydro-4-oxo-3-quinolnecarboxylic acid. The applicant has not shown an unexpected result in the formation of these salts. The applicant should provide a declaration showing unexpected results for the claimed compounds over those of the generic prior art compounds.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

BMR

7/8/03

*Alan L. Rotman*

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